

60th Medical Group (AMC), Travis AFB, CA
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20140038A

DATE: 14 August 2015

PROTOCOL TITLE: "Partial Resuscitative Endovascular Balloon Occlusion of the Aorta (P-REBOA) in a pig model (*Sus scrofa*)."

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Maj Lucas Neff

DEPARTMENT: General Surgery

PHONE #: 423-5179

INITIAL APPROVAL DATE: 28 August 2014

LAST TRIENNIAL REVISION DATE: N/A

FUNDING SOURCE: Surgeon General

1. RECORD OF ANIMAL USAGE:

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
<i>Sus scrofa</i>	21	15	15

2. PROTOCOL TYPE / CHARACTERISTICS: (Check all applicable terms in **EACH** column)

<input type="checkbox"/> Training: Live Animal	<input type="checkbox"/> Medical Readiness	<input type="checkbox"/> Prolonged Restraint
<input type="checkbox"/> Training: non-Live Animal	<input type="checkbox"/> Health Promotion	<input type="checkbox"/> Multiple Survival Surgery
<input type="checkbox"/> Research: Survival (chronic)	<input type="checkbox"/> Prevention	<input type="checkbox"/> Behavioral Study
<input checked="" type="checkbox"/> Research: non-Survival (acute)	<input type="checkbox"/> Utilization Mgt.	<input type="checkbox"/> Adjuvant Use
<input type="checkbox"/> Other ()	<input type="checkbox"/> Other (Treatment)	<input type="checkbox"/> Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable) ☐ C ☒ D ☐ E

4. PROTOCOL STATUS:

***Request Protocol Closure:**

☐ Inactive, protocol never initiated

☐ Inactive, protocol initiated but has not/will not be completed

☒ Completed, all approved procedures/animal uses have been completed

5. Previous Amendments:

List all amendments made to the protocol.. IF none occurred, state **NONE**. Do not use N/A.

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
<u>1</u>	23 Oct 2014	Technique Changes
<u>2</u>	21 May 2015	Personnel addition

6. **FUNDING STATUS:** Funding allocated: \$21,840.00 Funds remaining: \$ 0.00

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? ☒ Yes ☐ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

Dr. Sarah –Ashley Ferencz

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

None.

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

None.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

10. **PUBLICATIONS / PRESENTATIONS:** (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

A manuscript is being prepared for submission to the Journal of Trauma.

11. **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

Yes, the protocol objectives were met. The results indicate that partial REBOA may reduce or eliminate the physiologic insult and tissue damage that is caused by complete REBOA.

12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

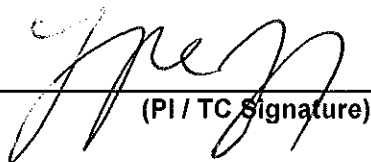
Objectives: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is used to salvage patients in shock from non-compressible torso hemorrhage. Previous experiments in swine have demonstrated that REBOA increases central blood pressure at the expense of distal organ perfusion. Partial REBOA (p-REBOA) may maintain central blood pressure while decreasing tissue ischemia distal to the balloon. We investigated the hemodynamic and physiologic effects of p-REBOA versus the current complete REBOA (c-REBOA) technique.

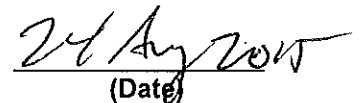
Methods: Fifteen Yorkshire-cross swine were anesthetized, instrumented, splenectomized, and subjected to 25% total blood volume loss over 20 minutes. They were then randomized to treatment with either c-REBOA,

p-REBOA, or no intervention. Aortic pressures (proximal and distal to the balloon), visceral arterial pressures, and serum makers of ischemia and inflammation were recorded throughout the experiment. P-REBOA was achieved by inflating the balloon catheter to generate a 50% pressure gradient across the balloon. Aortic balloons remained inflated for 90 minutes in the p-REBOA and c-REBOA groups and uninflated in the control group. Following balloon deflation, the experiment continued for 15 minutes to evaluate the effects of reperfusion. Following euthanasia, end organs were histologically examined.

Results: Compared with no treatment, c-REBOA produced considerable increases in central aortic pressure after hemorrhage but also substantially higher levels of serum lactate, followed by a precipitous drop in blood pressures on balloon deflation. p-REBOA was achieved by 80-90% aortic occlusion and resulted in hemodynamic effects that were superior to control while maintaining a lactate profile similar to control. Qualitative histological analysis of intestinal mucosa revealed early necrosis and disruption of the villi with c-REBOA and normal-appearing villi in the p-REBOA and control group.

Conclusion: This initial investigation indicates that p-REBOA may minimize the systemic physiologic insult and damage to tissues distal to the balloon. Further work with a model of ongoing hemorrhage is needed to determine if the hemodynamic improvements associated with p-REBOA will translate into a survival benefit in the face of persistent blood loss.


(PI / TC Signature)


(Date)

Attachments:

Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission (Mandatory)

Attachment 1**Defense Technical Information Center (DTIC) Abstract Submission**

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objectives: We investigated the hemodynamic and physiologic effects of partial Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) versus the current practiced complete REBOA (c-REBOA) technique.

Methods: Fifteen Yorkshire-cross swine were subjected to 25% total blood volume loss. They were randomized to either c-REBOA, p-REBOA, or no intervention. Aortic pressures, visceral arterial pressures, and serum makers of ischemia were recorded throughout the experiment. P-REBOA was achieved by inflating the balloon catheter to generate a 50% pressure gradient across the balloon. Following balloon deflation, the experiment continued for 15 minutes to evaluate the effects of reperfusion. End organs were histologically examined.

Results: Compared with no treatment, c-REBOA produced considerable increases in central aortic pressure after hemorrhage but also substantially higher levels of serum lactate, followed by a precipitous drop in blood pressures on balloon deflation. p-REBOA resulted in hemodynamic effects that were superior to control while maintaining a similar lactate profile. Histological analysis of intestinal mucosa revealed early necrosis and disruption of the villi with c-REBOA, but not in the p-REBOA and control group.

Conclusion: p-REBOA may minimize the systemic physiologic insult and damage to tissues distal to the balloon.

Grant Number: _____

From: _____

****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**